

Accordingly, Applicants request reconsideration and withdrawal of the rejection of the claims for obviousness-type double patenting.

Claims 9-27 were rejected under 35 U.S.C. § 112, first paragraph, because the examiner alleges that the term "a multiplicity of internal elements" in claims 9 and 18 are not described in the specification.

Applicants respectfully traverse this rejection.

The present invention relates to systems and processes for preparing and analyzing samples taken from biological fluid donations in order uniquely identify donations which are virus contaminated by performing high-sensitivity testing on a multiplicity of samples. The manner in which a unique identification is made from a multiplicity of samples can be aptly described in terms of mathematical matrix manipulation as described expressly in connection with FIGs. 13 and 14.

As is well understood by those having skill in the art, matrices are defined by their elements, without which the term "matrix" would be nonsensical. Since a matrix is bounded, all of its elements are necessarily internal to the matrix. Thus, the use of the term "internal elements".

However, in the interests of clarity, the offending term "internal" has been removed from claims 9 and 18. The N-dimensional matrix, referred to in the claims, is now more clearly set forth as comprising "a multiplicity of elements, each element defined by an intersection of the N-dimensions of the matrix . . .".

Given the amendments to claims 9 and 18, Applicants respectfully submit that the Examiner's rejection of claims 9-27 under 35 U.S.C. § 112, first paragraph, is now moot. Withdrawal of the rejection and early passage to issue is respectfully solicited.

Claims 18-27 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. In particular, the examiner has objected to the term "the method of minors" because it is unclear how "minors" is defined in the specification.

Applicants respectfully traverse this rejection.

As referred to above, the present invention is directed to a high-sensitivity testing methodology which uniquely identifies particular biological fluid donations having positive indications for viral contamination. A large number of donations may undergo high-sensitivity testing in a single analysis cycle by evaluating the test results according to a matrix.

As discussed in the specification at page 30 from lines 29 to 37 and page 31, lines 3 to 7, a number of sub-pools, or minor pools, are created with particular identifiers, with "the creation of the minor pools, in accordance with the invention, . . . viewed as being similar to the mathematical method of reducing a determinant by the method of minors."

Reducing a determinant by the method of minors is a well understood operation long known and practiced in the mathematical arts. Indeed, the methodology is sometimes referred to as "Laplacian development by minors". A complete description of its characterization and use may be found in any college level mathematics textbook.

Accordingly, Applicant respectfully submits that there is no ambiguity in the term "the method of minors" and respectfully solicits reconsideration and withdrawal of the rejection of claims 18-27 under 35 U.S.C. § 112, second paragraph.

With regard to Applicant's information disclosure statements PTO/1449, filed May 20, 1998 and September 21, 1998, the Examiner has not considered several of the citations because the references are allegedly not available in the parent application.

Applicant's wish to call the Examiner's attention to the facial pages of U.S. Patent No. 5,780,222, a copy of which is enclosed, in which all of the references cited in Applicant's forms PTO-1449 are shown. Applicants would respectfully submit that the lined-through references are indeed of record in the parent case of the present application.

However, in order to ensure that these references are considered by the Examiner, Applicants submit herewith an additional form PTO-

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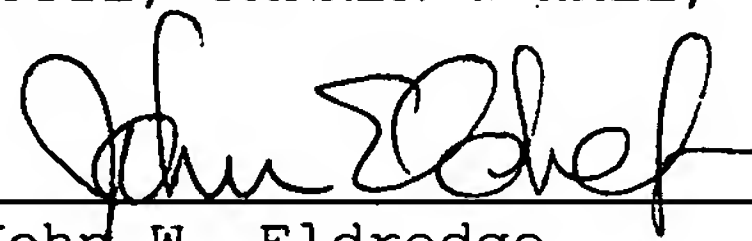
1449 listing the references at issue and enclose copies of the cited references for the Examiner's files. Because these references were timely cited and because each of the references are of record in the parent case, Applicants submit that a certification or fee under 35 CFR § 1.97 are unnecessary.

No further matters remaining outstanding, applicants suggest that the application is in condition for allowance. A notification of same and early passage to issue are respectfully solicited.

Respectfully submitted,

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Enclosures: Terminal Disclaimer
Facial page of U.S. 5,780,222
Supplemental Form PTO-1449 and cited references